

DEC 01 2008

This report is required by law (7 USC 2143). Failure to report according to the regulations can result in an order to cease and desist and to be subject to penalties as provided for in Section 211.

See attached form for additional information.

Interagency Report Control No.:

UNITED STATES DEPARTMENT OF AGRICULTURE  
ANIMAL AND PLANT HEALTH INSPECTION SERVICE

1. CERTIFICATE NUMBER: 51-F-0024

CUSTOMER NUMBER: 12776

FORM APPROVED  
OMB NO. 0579-0068

ANNUAL REPORT OF RESEARCH FACILITY  
(TYPE OR PRINT)

Center For Biologics Evaluation & Research  
29 Lincoln Drive  
Bethesda, MD 20852

Telephone: (b)(6), (b)(7)c

3. REPORTING FACILITY (List all locations where animals were housed or used in actual research, testing, or experimentation, or held for these purposes. Attach additional sheets if necessary.)

FACILITY LOCATIONS (Sites) - See Attached Listing

REPORT OF ANIMALS USED BY OR UNDER CONTROL OF RESEARCH FACILITY (Attach additional sheets if necessary or use APHIS Form 7023A)

A. Animals Covered By The Animal Welfare Regulations	B. Number of animal being bred, conditioned, or held for use in teaching, testing, experiments, research, or surgery but not yet used for such purposes.	C. Number of animals upon which teaching, research, experiments, or tests were conducted involving no pain, distress, or use of pain-relieving drugs.	D. Number of animals upon which experiments, teaching, research, surgery, or tests were conducted involving accompanying pain or distress to the animals and for which appropriate anesthetic, analgesic, or tranquilizing drugs were used.	E. Number of animals upon which teaching, experiments, research, surgery or tests were conducted involving accompanying pain or distress to the animals and for which the use of appropriate anesthetic, analgesic, or tranquiliz- ing drugs would have adversely affected the procedures, res- ults or interpretation of the teaching, research, experiments, surgery, or tests. (An explanation of the procedures producing pain or distress in these animals and the reason such drugs were not used must be attached to this report)	F. TOTAL NUMBER OF ANIMALS (COLUMNS C + D + E)
4. Dogs					
5. Cats					
6. Guinea Pigs		207	68	15	290
7. Hamsters		516	9	0	525
8. Rabbits		54	0	0	54
9. Non-human Primates	23	68	5	0	96
10. Sheep		7	0	0	7
11. Pigs					
12. Other Farm Animals					
13. Other Animals					
Ferrets		45	0	0	45
Horses		2	0	0	2

ASSURANCE STATEMENTS

- 1) Professionally acceptable standards governing the care, treatment, and use of animals, including appropriate use of anesthetic, analgesic, and tranquilizing drugs, prior to, during, and following actual research, testing, surgery, or experimentation were followed by this research facility.
- 2) Each principal investigator has considered alternatives to painful procedures.
- 3) This facility is adhering to the standards and regulations under the Act, and it has required that exceptions to the standards and regulations be specified and explained by the principal investigator and an Institutional Animal Care and Use Committee (IACUC). A summary of all such exceptions is attached to this annual report. In addition to identifying the IACUC-approved exceptions, this summary includes a brief explanation of the exceptions, as well as the species and number of animals affected.
- 4) The attending veterinarian for this research facility has appropriate authority to ensure the provision of adequate veterinary care and to oversee the adequacy of other aspects of animal care and use.

CERTIFICATION BY HEADQUARTERS RESEARCH FACILITY OFFICIAL  
(Chief Executive Officer or Legally Responsible Institutional Official)

SIGNATURE (b)(6), (b)(7)c

DATE SIGNED

11/24/08

NP

### Optional Column E Explanation Form

This form is intended as an aid to completing the Column E explanation. It is not an official form and its use is voluntary. Names, addresses, protocols, veterinary care programs, and the like, are not required as part of an explanation. A Column E explanation must be written so as to be understood by lay persons as well as scientists.

---

1. Registration Number: 51-F-0024
2. Number of animals used in this study subject to column E listing: 15
3. Species (common name) of animals used in this study: Guinea Pigs
4. Explain the procedure producing pain and/or distress.

ASP# 89-32. This is a potency test that evaluates the presence of sufficient protective antigen in toxoids manufactured to prevent tetanus and diphtheria in humans. It is performed by CBER as a lot release test to verify adequate protection to the U.S. population by vaccines licensed in the U.S. Animals are injected with a combination of toxin and protective antibodies and survival is determined out to 7 days. Protected pigs show no signs, but control animals and inadequately protected animals will develop signs of disease and proceed to death rapidly without the benefit of euthanasia. Historically, 10 % of the total number of animals used have died as a result of toxin administration and therefore have fallen under column E.

5. Provide scientific justification why pain and/or distress could not be relieved. State methods or means used to determine that pain and/or distress relief would interfere with test results. (For Federally mandated testing, see question 6 below).

As required by the Minimum Standards (which are the precursors to the CFR) animals which become sick before 96 hours cannot be euthanized. After 96 hours and up until the end of the test of 7 days, any animals showing signs of disease can be euthanized. There is no in vitro alternative for potency testing these two components of the U.S. Childhood Vaccination Program.

6. What, if any, federal regulations require this procedure? Cite the agency, the Code of Federal Regulations (CFR) title number and the specific section number (e.g., APHIS, 9 CFR 113.102):  
This test is required by the FDA Minimum Standards Requirements.